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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,161	08/24/2001	Richard W. Voellmy		4118

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EXAMINER

OH, SIMON J

ART UNIT

PAPER NUMBER

1615

DATE MAILED: 08/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,161

Applicant(s)

VOELLMY, RICHARD W.

Examiner

Simon J. Oh

Art Unit

1615

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 May 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Papers Received

Receipt is acknowledged of the applicant's response, received on 12 May 2003.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1-15, 21, and 22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for diamide, geldanamycin, sodium arsenite, stannous chloride, zinc chloride, and an activated heat shock transcription factor 1 in protein or nucleic acid form, does not reasonably provide enablement for all benzoquinone ansamycin compounds, all arsenic salts, all tin salts, and all zinc salts. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The factors to be considered in determining whether a disclosure meets the enablement requirement of 35 U.S.C. 112, first paragraph, have been described in *In re Wands*, 8 USPQ2d 1400 (Fed. Cir. 1988). Among these factors are: (1) the nature of the invention; (2) the state of the prior art; (3) the relative skill of those in the art; (4) the predictability or unpredictability of the art; (5) the breadth of the claims; (6) the amount of direction or guidance presented; (7) the presence or absence of working examples; and (8) the quantity of experimentation necessary.

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When the above factors are weighed, it is the examiner's position that one skilled in the art could not practice the invention without undue experimentation.

(1) The nature of the invention:

The invention provides methods for protecting a human patient or a mammalian animal to be subjected to chemotherapy treatment of a tumor not residing in the scalp of the patient or the skin of the animal against chemotherapy-induced alopecia, comprising administering to the scalp of the patient or the skin of the animal an effective amount of a composition comprising a chemical inducer of the stress protein response sufficiently prior to the administration of a chemotherapeutic drug.

(2) The state of the prior art

Although various methods of preventing and treating chemotherapy-induced alopecia are known in the prior art, by the applicant's own disclosure, the success of such techniques are greatly influenced by a number of factors, including the gender of the patient, the half-life of the chemotherapy agent, and whether the chemotherapy treatment includes only one agent or a combination of agents. Disadvantages of the methods of the prior art include the toxicity imparted by the treatments, patient discomfort, and the administration of therapeutic compounds weeks prior to chemotherapy. Furthermore, by the applicant's own disclosure, relatively little research has been conducted to identify the actual mechanisms of chemotherapy-induced alopecia.

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(3) The relative skill of those in the art

The relative skill of those in the art is high.

(4) The predictability or unpredictability of the art

The unpredictability of the art is high. In methods of treating a condition, a time-dependence factor must be taken into account. In methods of preventing a condition, the time-dependence factor cannot be easily predicted. Furthermore, as the Background section of the Jimenez *et al.* patent reveals, therapeutic agents must be tested for effectiveness against specific, individual chemotherapy agents.

(5) The breadth of the claims

The claims are very broad. The methods claims primarily require the administration of a broadly defined group of active agents (that is, diamide, benzoquinone ansamycin compounds, arsenic salts, tin salts, zinc salts, and an activated heat shock transcription factor 1 in protein or nucleic acid form), along with a penetration enhancer and a carrier, with the agent being administered at a sufficient length of time before the administration of a chemotherapeutic drug.

(6) The amount of direction or guidance presented

Throughout the specification, the applicant has disclosed that treatment parameters, such as the amount of time the treatment is to be administered before chemotherapy, and the amount of the treatment agent to be used depends on various factors, which include the penetration enhancer used, as well as the pharmaceutical carrier used, and the specific manner in which the

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agent is administered. Furthermore, the applicant has disclosed that such treatment parameters are to be determined empirically, using various methods, including animal modeling. In the view of the examiner, this is interpreted to say that such treatment parameters cannot be predicted or roughly estimated without conducting such testing.

(7) The presence or absence of working examples

Although the applicant has disclosed experimental procedures in detail, actual experimental results demonstrating the effectiveness of the instantly claimed invention have been provided only for sodium arsenite and HSF(+).

(8) The quantity of experimentation necessary

Since the treatment parameters, especially with respect to the type and amount of therapeutic agent to be used, cannot be predicted *a priori* but must be determined from the case to case by painstaking experimental study and when the above factors are weighed together, one of ordinary skill in the art would be burdened with undue “painstaking experimentation study” to determine proper dosage amounts of each therapeutic agent to be used to treat a patient being administered a particular chemotherapeutic agent, as well as to determine the length of time between the administration of the treatment and the start of chemotherapy.

Claim Rejections - 35 USC § 102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

The rejection of Claims 1, 10, 16, 17, and 20 under 35 U.S.C. 102(b) as being anticipated by Li *et al.* is hereby withdrawn.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 1-22 are rejected under 35 U.S.C. 103(a) as being unpatentable over Li *et al.* in view of Jimenez *et al.* is maintained.

Response to Arguments

Applicant's arguments filed 12 May 2003 have been fully considered but they are not persuasive. Applicant's arguments appear to be predicated on a narrow interpretation of both the claims and the prior art, particularly with respect to the disclosure of Column 4 of the Li *et al.* patent. It is the position of the examiner that one of ordinary skill in the art, giving both the prior art and the claims in their present form their broadest reasonable interpretation, would find the claimed invention obvious in view of the prior art. See MPEP § 2111 and 2123.

As the applicant himself has stated in the arguments filed 12 May 2003, the rejection set forth in the previous office action may read on one member of the Markush group in Claims 2, 4, 7, 9, 13, 15, 17, and 22. Rejection of one member of a Markush group, in accordance with Office policy, is sufficient for an obviousness-type rejection under 35 U.S.C. 103, since each member of the Markush group is recognized as belonging to a broader class recognized by the

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art. Thus, the rejection under 35 U.S.C. 103 previously set forth is deemed proper and will be maintained.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Simon J. Oh whose telephone number is (703) 305-3265. The examiner can normally be reached on M-F 8:30 am to 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1234.

Simon J. Oh
Examiner
Art Unit 1615

sjoh
August 8, 2003

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600